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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ADVIA® Centaur

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K041133

1. Intended Use

The *Bayer ADVIA Centaur* assay is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assay analysis on clinical specimens. The system menu will include endocrine, anemia, allergy, reproductive, cardiovascular, oncology, adrenal, bone metabolism, therapeutic drug, and infectious disease assays. All assays are based on chemiluminescent technology.

2. Predicate Device

Proprietary Name: Bayer ADVIA Centaur Analyzer
Common name: Automated Immunoassay Analyzer
Classification name: Photometric Analyzer for Clinical Use
Classification number: 21 CFR 862.2160, Class I
510(k) Number: K032525

3. Device Information

Proprietary Name: Bayer ADVIA Centaur Analyzer
Common name: Automated Immunoassay Analyzer
Classification name: Photometric Analyzer for Clinical Use
Classification number: 21 CFR 862.2160, Class I

4. Device Description

The ADVIA Centaur system is a stand-alone, continuous operation, immunochemistry analyzer. The system performs the following functions:

- Aspirates and dispenses samples
- Performs dilutions
- Adds reagents
- Incubates reaction vessels
- Separates solid and liquid wastes
- Measures photon emissions
- Performs data reduction
- Collects and maintains patient demographics and results

5. Summary of Technological Characteristics

Assays that are dedicated for use on the ADVIA Centaur utilize acridinium ester as label and paramagnetic particles as the solid phase. The ADVIA Centaur measures the amount of light emitted during the chemiluminescent reaction. There is a direct relationship between the amount of light emitted and the amount of ligand in the patient sample. The system will measure both competitive binding assays and sandwich assays.

The ADVIA Centaur system uses a Master Curve and a two-point, user-initiated calibration to calibrate all the assays. The Master Curve and the two-point calibration system eliminate the need to measure a full standard curve with each assay or to run calibrators each time the assay is run. The system stores the calibration for the interval specified in the assay product inserts.

A comparison table of Technological Features is included below:

Feature	**ADVIA Centaur V2.5** (K032525)	**ADVIA Centaur V3.0**
Principles of Operation	- Chemiluminescence using magnetic-particle solid phase and chemiluminescent label	same
Optical System	- PMT used in photon counting mode	same
Temp control	- Reactions are controlled at 37°C	same
	- Reagent Storage:	
	- Reagents stored at 4°C to 8°C	same
Dispense System	- Automated pipetting of samples and reagents	same
	- Precision syringes (sample and reagent)	same
	Sample Probe :	
	· Air pressure fluid sensing	same
	· Air pressure disposable tip sensing	same
	· Clog detection mechanism to alert operator to clogged sample probe	same
	Reagent Probes:	
	· No level sense; probe sent to bottom of container	same
	· Fluid monitoring during aspiration	same
Reagent and Sample Handling	- Samples: 5 tube racks hold sample tube. The Sample Input, In-Process and Output Queue holds up to 180 samples; Tube size selected on sample tube rack using an encoded barcode.	same
	- Assay Reagents: Reagent Tray with 30 positions; Refrigeration; Reagent Pack contains both Solid Phase and Tracer Reagent in separate wells	same

	- Ancillary Reagents: Reagent Compartment with 15 positions; Refrigeration	same
Test Processing	Random Access and Batch	same
	- Sample scheduling optimized for throughput; Continuous Operation	same
Assay Protocols	- 7.5 minute incubation, single step	same
	- 20 minute incubation, single step	same
	- 7.5 - 20 minute incubation, two step	same
	- 20 - 20 minute incubation, two Step	same
Human Interface - data Output	- 17" Color Monitor with Graphical User Interface	same
	- External printers	same
	- Serial bi-directional LIS Interface	same
	- Audible (adjustable) beeper	same
	- Computer LIS Interface	same
	- External Modem for Remote Diagnostics Interface	same
Human Interface - data Input	- 101 key keyboard	same
	- Hand-held barcode reader	same
	- Stationary barcode scanners for id of patient samples	same
	- Moving Barcode reader for primary reagents	same
	- Computer LIS Interface	same
	- LIS Software Enhancements	same
Human Interface - data analysis	- Automated data reduction	same
	- Assay-specific data reduction	same
QC Software	- Stored control results	same
	- L-J plotting	same
	- Statistical enhancements	same
	- Compatibility with CCD QC Reporting	same
	- Added New Features to QC Functionality	same
Specimens	- Serum or plasma, sample cups or primary tubes may be used	same
	- Dilutions allowed on a per-assay basis	same
	- Capability of Dilution of Samples Requiring Pretreatment	same
Disposables	- Sample cups	same
	- Reaction cuvettes	same
	- Cuvette loading and unloading allowed during run	same
	- Reagent I & 2 status tracked and displayed	same
	- Additional wash solutions (status tracked and displayed)	same
	- Sample Pipette Tips	same
	- All disposables may be loaded during operation	same
	- All waste may be unloaded during operation	same

Reagents	- Solid Phase	same
	- Chemiluminescent label (Acridinium Ester)	same
	- Reagent volume reporting	same
	- Reagent inventory tracks bottle usage	same
	- Ancillary Reagents with inventory tracking and volume reporting	same
Calibrators	- 6 to 10 point stored calibration for each reagent	same
	- 2 point user run calibration	same
	- Calibrators checked with barcode	same
	- Calibrator lot numbers stored and displayed	same
Controls	- Low, mid, and high constituent controls	same
	- Capability to dilute controls	same
Physical	- Floor Model-, 60Hx42Dx58L	same
	- 1200 lbs.	same
	- <2000 watts	same
	- ambient temp 18-30C	same
Laboratory Automation	Software signals for direct sampling from the sample transport system.	same
Other User Interface Features	- Stat interrupt capability	same
	- Automated system cleaning	same
	- Graphical User Interface for scheduling batch runs, report options, easy-to-use maintenance	same
	- Complete reporting of system status and logging of system events	same
	- Tracking on-board reagent usage	same
	- Support for foreign languages: French, Italian, German, and Spanish language availability	same
	- Multiple barcode formats supporting including, 128, 2 of 5,Code39,Codabar	same
	- On-Line Information System(help)	same
	- System test extended to include slope and offset, dilution and overrange condition	same
		same
Other Performance Features	- Throughput: 120 to 240 tests/hr	same
	- Time to First Result: 15 min., 30 min., 60 min. depending upon assay protocol	same
	. On-board supplies for 1000 tests (cuvettes,water,waste capacity)	same

Software	Unix based graphical User interface, Multiple distributed real-time computing platforms with capabilities to communicate to LIS and LAS systems.	Same, except for additional features as follows:
	New Reports-maintenance,event log, reagent tracking.	same
		Control Bracketing Software
		Restricted Test Mode
		Transmission of Ratio Component
		Repeat with Replicates
Hardware Improvements	Hitachi/ Unviersal rack option added	same
	High Resolution Barcode Scanner (LS4000i) released.	same

Carl Zu

4/21/2004

Date

Andres Holle
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 2 2004

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer Healthcare, LLC.
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591

Re: k041133
Trade/Device Name: ADVIA® Centaur
Regulation Number: 21 CFR 862.1810
Regulation Name: Vitamin B_{12} test system
Regulatory Class: Class II
Product Code: CDD, CDP, CDZ, CEC, CEP, CFT, CGJ, CGN, CHP, DBF, DDR, DGC, DHX, DIS, DKB, JFT, JHI, JHX, JJE, JJX, JKD, JLS, JLW, JZO, KHQ, KLT, KXT, LCD, LCR, LEH, LFM, LFX, LGD, LGR, LGS, LOQ, LPS, LTK, MMI, MOI, NBC, NIG
Dated: June 7, 2004
Received: June 9, 2004

Dear Mr. Holle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, D.V.M.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041133

Device Name: ADVIA® Centaur

Indications For Use:

The *Bayer ADVIA Centaur* is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assay analysis on clinical specimens. The system menu will include endocrine, anemia, allergy, reproductive, cardiovascular, oncology, adrenal, bone metabolism, therapeutic drug, and infectious disease assays. All assays are based on chemiluminescent technology.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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